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Pursuant to Local Rule 16.5(d) and the Court's Amended Litigation Scheduling Order dated July 29, 2014 (ECF No. 468) (the "Amended Scheduling Order"), the parties respectfully submit this Joint Pre-trial Memorandum.

I. SUMMARY OF EVIDENCE

A. Plaintiffs' Summary of the Evidence

A concise summary of the evidence to be offered by Plaintiffs at trial is attached as Exhibit A.

B. Defendant's Summary of the Evidence

A concise summary of the evidence to be offered by Defendant at trial is attached as Exhibit B.

II. STIPULATIONS OF FACT

The parties stipulate to the facts set forth in the attached Stipulations of Undisputed Facts, attached as Exhibit C.

III. CONTESTED ISSUES OF FACT

The parties dispute the following factual issues:

A. Plaintiffs' Contested Factual Issues

1. Whether Astellas's petition and/or supplement were a sham.
2. Whether Astellas's certification accompanying its petition supplement was false.
3. Whether Astellas is a monopolist.
4. Whether the direct purchaser class incurred antitrust injury stemming from Astellas's petitioning activity.
5. The amount of damages.

B. Defendant's Contested Factual Issues

1. Whether Astellas's request in its Citizen Petition for FDA to require manufacturers of orally administered immunosuppressants used in the transplant population and characterized by a narrow therapeutic index, such as tacrolimus, to supplement bioequivalence studies in healthy subjects with studies performed in the transplant population, was objectively baseless.

2. Whether Astellas's request in its Citizen Petition for FDA to require changes to the labeling for orally administered immunosuppressants used in the transplant population and characterized by a narrow therapeutic index, such as tacrolimus, to require that prescribing physicians be notified of a substitution between formulations of such drugs so that the physician may institute appropriate blood concentration monitoring of the patient, was objectively baseless.

3. Whether Astellas's request in its Citizen Petition to require manufacturers of substitute oral formulations of narrow therapeutic index drugs for use in transplant, such as tacrolimus, to provide prominent dosage strength information and to clearly differentiate between sources so that patients, physicians and pharmacists know when the sourcing has changed, was objectively baseless.

4. Whether Astellas's only objective in filing the Petition was to use the governmental process of the FDA's consideration of its Citizen Petition to delay the market entry of generic versions of Prograf.

5. Whether the FDA would have approved Sandoz's generic tacrolimus products earlier than August 10, 2009, if Astellas had not filed the Citizen Petition, and if so, when Sandoz's generic tacrolimus products would have entered the U.S. market but for the Citizen Petition.

6. The amount of damages, if any, sustained by the Plaintiffs.

IV. JURISDICTIONAL QUESTIONS

The parties are not aware of any jurisdictional issues.

V. PENDING MOTIONS

A list of the motions pending before the Court is attached as Exhibit D.

VI. ISSUES OF LAW AND EVIDENTIARY QUESTIONS

The parties have addressed certain issues of law, including evidentiary questions, through their motions *in limine*, *Daubert* motions, and other evidentiary motions listed in Exhibit D.

The parties will address additional issues of law, including evidentiary questions, through their proposed jury instructions, to be submitted January 5, 2015.

VII. AMENDMENT TO THE PLEADINGS

The parties do not plan any amendments at this time. Each party reserves the right to amend its pleadings to conform to the evidence at trial.

VIII. ADDITIONAL MATTERS TO AID IN THE DISPOSITION OF THE ACTION

A. Federal Rule of Evidence 1006 Summaries

1. Plaintiffs' Proposal

The parties intend to offer into evidence a series of summaries under Federal Rule of Evidence 1006. After admission of the documents that are summarized in the Rule 1006 summary, a person would be permitted to read selected portions of the summary, in an objective and neutral manner, into the record. If otherwise admissible, the summary itself shall also be received into evidence. Pursuant to the Court's Pre-Trial Order, the parties will exchange Rule 1006 summaries on December 1, 2014. The parties reserve all rights to object to the submission or use of such summaries pending review and meet and confer.

2. Defendant's Proposal

Defendant agrees with Plaintiffs' proposal, but opposes Plaintiffs' proposal that "a person would be permitted to read selected portions of the summary" before the summary is received into evidence.

B. Exhibit Books for Jurors

1. Plaintiffs' Proposal

Each side may provide the jurors with individual notebooks containing key exhibits selected by that party. The parties may update the binders with an updated table of contents and additional exhibits as the trial progresses. No party may provide the jurors with more than 25 exhibits for their binders.

2. Defendant's Proposal

Defendant disagrees with Plaintiffs' proposal to provide the jurors with 50 "key exhibits" (25 exhibits from each party) because it would be burdensome and unwieldy. Defendant proposes that the parties provide the jurors with agreed-upon individual notebooks containing up to 10 key exhibits selected and agreed-upon by all parties. The parties will submit the agreed-upon exhibit books to the Court by January 5, 2015.

C. Note Taking by Jurors

1. Plaintiffs' Proposal

Jurors will be permitted to take notes in notebooks that the Court will provide. The jurors will be given a preliminary instruction about note taking. During recesses, jurors will be required to leave their notebooks in the courtroom on their seats. At the end of each day, the notebooks will be collected by the clerk, and they will be placed back on the jurors' seats at the commencement of the trial on the following day. At the end of the trial, the jurors will be permitted to take their notebooks to the jury room for use during deliberations. At the end of deliberations, any notes taken by jurors will be destroyed.

Defendant seeks to have the notebooks also include the names and photographs of each witness who will testify at trial. The parties will provide the names and agreed-upon photographs to the Court by January 5, 2015. Plaintiffs oppose this request as unnecessary, burdensome, distracting, and prejudicial.

2. Defendant's Proposal

Defendant agrees with Plaintiffs' proposal, and also proposes that the notebooks include the names and photographs of each witness who will testify at trial. The parties will provide the names and agreed-upon photographs to the Court by January 5, 2015.

D. Juror Questions

After all counsel have completed their examinations of a witness, jurors will be permitted to submit questions to the witness pursuant to the following procedure:

(A) During the Court's preliminary instructions, jurors will be told that they will be permitted to submit written questions to the Court after counsel have completed their examination of a witness. The Court's preliminary instructions will also include an admonition to the jury that if they decide to ask a question, that they should do so as a neutral judge of the facts and not as a partisan advocate for one side or the other. Moreover, the jurors will be told that the Court may not be able to ask a witness a proposed question for a variety of reasons, including legal reasons. The jurors will also be instructed that if the Court does not ask one of their questions, they cannot speculate about why the Court declined to ask it, or what the answer would have been; they are to treat the question as if it was never asked.

(B) When a written question is submitted by a juror, the question will be reviewed by the Court with counsel, who will be given the opportunity to lodge any objections. The Court will either sustain the objection and not submit the question to the witness or overrule the objection and submit the question to the witness through the Court.

E. Proposed Preliminary Instructions

1. Plaintiffs' Proposal

In addition to the Court's customary preliminary instructions to jurors, Plaintiffs request that the Court give additional preliminary instructions to the jurors in the nature of background information (approximately 5 pages per subject) on two subjects: (1) a basic explanation of petitions, *e.g.*, what they are, how they are presented to the FDA, and what they must contain; and (2) a basic primer on generic drugs, *e.g.*, what they are, the standards for FDA approval, how they are dispensed by pharmacies. The parties will meet and confer in an effort to provide the Court with an agreed set of preliminary instructions on these subjects. Failing agreement, the parties will submit proposed preliminary instructions on these subjects to the Court by January 5, 2015.

2. Defendant's Proposal

Defendant opposes Plaintiffs' request that the Court give 10 pages of proposed additional preliminary instructions on the two subject identified by Plaintiffs because such instructions are unnecessary, burdensome, and potentially prejudicial, especially as the topics Plaintiffs propose involve numerous disputed issues of fact and law. For example, Plaintiffs want to include in the preliminary instruction "what [Citizen Petitions] must contain"—an issue that the Court knows is hotly contested and the subject of extensive expert discourse—and "how [generic drugs] are dispensed by pharmacies"—an issue that varies by state and by the requirements of the payor.

F. Demonstrative Exhibits

The parties previously agreed to, and the Court approved, a procedure for exchange and approval of demonstrative aids. *See* Amended Scheduling Order ¶ 10.

G. Documents Not Previously Disclosed

1. Plaintiffs' Proposal

The parties reserve their right to supplement their exhibit lists up to and during trial for good cause shown. Any document not identified on an exhibit list may be used at trial solely for purposes of impeachment. Any deposition or portion thereof not specifically designated may still be used at trial solely for purposes of impeachment. The “good cause shown” limitation on supplementation allows the parties to offer relevant evidence not anticipated in good faith through the pretrial proceedings, while guarding against abuse.

2. Defendant's Proposal

The parties previously exchanged lists of the exhibits they expect to offer and those it may offer if the need arises pursuant to FRE 26(a)(3)(A)(iii). *See* Amended Scheduling Order ¶ 8. Defendant disagrees that the parties can supplement exhibit lists outside of the previously agreed-upon procedure for exchanging exhibit lists and the Federal Rules of Evidence. *Id.* As the parties agreed and as stated in the Amended Scheduling Order, demonstrative aids, Rule 1006 summaries, and rebuttal exhibits did not need to be included on the exhibit lists. *Id.*

H. Enlargement of Exhibits

No advance notice of intent to enlarge an admitted or demonstrative exhibit or a portion thereof – with or without highlights – is required.

I. Order of Witnesses

Plaintiffs will provide Defendant a list of witnesses whom they in good faith intend to call on direct examination in the order in which they intend to call them and a good faith estimate of the length of the direct examination of each witness by close of business seven days before the start of trial.

Defendant will provide to Plaintiffs a list of witnesses whom they in good faith intend to call on direct examination in the order in which they intend to call them by 7:00 p.m. on the day that the trial starts.

The parties agree to provide the names of witnesses to be called in their rebuttal case, if any, by 7:00 p.m. two days prior to calling the witness.

If any party decides to change the order in which it intends to call its “will call” witnesses or drop any “will call” witness previously listed, that party will notify the opposing party as early as possible, but in no event later than 2:00 p.m. the day before those witnesses are intended to testify. If any party decides to change the order in which it intends to call its “may call” witnesses or drop any “may call” witness previously listed, that party will notify the opposing party as early as possible, but in no event later than 2:00 p.m. two days before those witnesses are intended to testify. Nothing in this paragraph is intended to revise or otherwise change any applicable rule(s) relating to securing the attendance of witnesses at trial. Without waiving the right of any party to object to producing the witness, if a party intends to call in its case an employee of an opposing party, the party desiring to call that employee shall provide the other party with two weeks’ notice and will endeavor in good faith to provide a reasonable estimate of when the witness will be called.

J. Use of Depositions

The parties will adhere to the procedure for exchange and approval of deposition designations set forth in Amended Scheduling Order ¶ 7 dated July 29, 2014 (Doc. 468-1), and Order dated November 25, 2014 (Doc. 611).

K. Opening Statements and Closing Arguments

The parties shall be allotted 60 minutes per side for opening statements and 90 minutes per side for closing arguments.

L. Witness Sequestration

1. Plaintiffs' Proposal.

The parties request that, except as otherwise directed by the Court, no fact witness shall be permitted as a spectator in the courtroom until all testimony from that witness (direct, cross, re-direct, re-cross) is concluded, and shall not review any trial transcripts until that witness has completed all trial testimony or has been removed from all parties' lists of trial witnesses, provided, however, that a corporate representative may be in the courtroom at all times, whether or not he or she is a fact witness and has or has not testified.

2. Defendant's Proposal.

Defendant agrees with Plaintiffs' proposal, except that all witnesses should be permitted to attend opening statements.

M. Service of Documents During Trial

Beginning five calendar days before the start of trial, service of documents, including but not limited to any pleadings and/or bench memoranda, will occur by email no later than 7:00 p.m. Overly large documents, including but not limited to any pleadings and/or bench memos that cannot be received effectively or efficiently by email will be served by hand delivery no later than 7:00 p.m. Service shall be made at least on the following representatives for each party:

For Direct Purchaser Plaintiffs:

David S. Nalven, Hagens Berman Sobol Shapiro LLP

Dan Litvin, Garwin Gerstein and Fisher LLP

Stuart E. DesRoches, Odom & DesRoches LLP

Hand deliveries to Direct Purchaser Plaintiffs shall be made to David S. Nalven, Hagens Berman Sobol Shapiro LLP, 55 Cambridge Parkway, Suite 301, Cambridge MA 02142.

For Defendant:

David Schiffman, Sidley Austin LLP

Jana Wozniak, Sidley Austin LLP

Michelle Ramirez, Sidley Austin LLP

Angelo Suozzi, Sidley Austin LLP

Hand deliveries to Defendant shall be made to Michelle Ramirez or Angelo Suozzi, at an address to be supplied at a future date.

The parties have agreed that when documents or exhibits are served in the courtroom (or at the courthouse), two full copies of the documents will be served on the designated representatives for service identified above.

The parties have agreed that beginning seven calendar days before the start of trial, the term “days” as used herein shall refer to calendar, as opposed to business days. This agreement ends when the trial is concluded.

N. Electronic Equipment

Each party will be permitted to use electronic equipment for the presentation of evidence and will be permitted to have no more than two technicians in the courtroom to operate such system. The parties will split the costs of any shared audio and video equipment used to present such evidence. No later than five days before trial, the parties will present to the Court a list of all audio and video equipment that will be used to present evidence during the trial and the names of the persons who will be responsible for delivering and setting up the equipment on the equipment set-up date, which will be provided by the Court.

The parties request that the Court grant access to the courtroom on the business day before trial for the purposes of setting up electronic and computer devices.

IX. LENGTH OF TRIAL

The parties and the Court have determined that the probable length of the trial will be three weeks (15 trial days, not including jury selection), assuming that trial days are about 3.75 hours in length. The time will be divided equally between the parties, with each side getting 28.5 hours of trial time.

X. WITNESSES WHO WILL TESTIFY AT TRIAL

A. Plaintiffs' Witness List

Plaintiffs hereby submit their list of witnesses that they intend to call or may call to testify at trial. This list is not a commitment that the Plaintiffs will call any particular witness at trial. Plaintiffs' witness list is attached as Exhibit E.

For good cause shown, Plaintiffs reserve the right to amend and supplement this list; to call all persons identified as witnesses by the Defendant; to call additional witnesses to authenticate, or otherwise lay the foundation for admission of, evidence, or for purposes of impeachment or rebuttal; to call any person whose deposition testimony has been designated by any party; and to supplement this list based upon the Court's rulings, including regarding *Daubert* and *in limine* motions, other motions, and any issues, exhibits, or witnesses presented by any party.

Plaintiffs' witness list includes Margaret Glazier, an employee of class representative Burlington Drug Company, Inc. Astellas objects to Ms. Glazier serving as a witness because she was not disclosed prior to the parties' exchange of witness lists on September 2, 2014. In their Rule 26 initial disclosures dated March 15, 2012, Plaintiffs identified Chris Mitiguy of Burlington Drug Company, Inc. as person with knowledge of Burlington Drug's claims. Mr. Mitiguy has left Burlington Drug and Ms. Ms. Glazier is his successor. Plaintiffs respectfully

request that Ms. Glazier be permitted to replace Mr. Mitiguy as a trial witness for Burlington Drug.

B. Defendant's Objections to Plaintiffs' Witnesses

Defendant hereby objects and responds to Plaintiffs' witness list. These objections and responses do not waive Defendant's right to object or move to exclude witness testimony and evidence pursuant to the Federal Rules of Evidence, the Amended Scheduling Order, or otherwise.

Specific Witness Objections.

Defendant objects to the designation of the following Astellas employees as "live" witnesses on Plaintiffs' witness list: Sharon Park and former employee, Charlotte Berlin for the reasons stated in Astellas's Opposition to Plaintiffs' Motion For Trial Testimony of Two Astellas Witnesses By Live Contemporaneous Video Transmission (Dkt. 614 (motion to seal)) and Opposition to Plaintiffs' Motion for Trial Testimony of Two Astellas Witnesses by Live Contemporaneous Video Transmission (Dkt. 612). Astellas objects that Margaret Glazier was not previously disclosed as required by the Federal Rules of Civil Procedure, either in Rule 26 Initial Disclosures or otherwise, and there is no evidence that the failure to disclose was justified.

General Objections.

Defendant objects to Plaintiffs' witness list and their reservations of rights to the extent that they fail to comply with the Federal Rules and the Amended Scheduling Order, and to the extent they seek to allow Plaintiffs to make changes and additions to its witness list without providing reasonable and timely notice of any change or addition to Astellas and without providing Astellas the opportunity to object to such changes. Defendant reserves the right to revise its objections, and to assert new objections, based on the Court's rulings (including but not limited to the Court's November 25, 2014 Order (Dkt. 611)).

C. Defendant's Witness List

Defendant's witness list is attached as Exhibit F.

D. Plaintiffs' Objections to Defendant's Witness

Plaintiffs' objections to Defendant's witnesses are encompassed by pending motions set forth in Exhibit D. Defendant will file responses in opposition to Plaintiffs' motions on or before the Joint Pre-Trial Conference on December 4, 2014 in accordance with D. Mass L.R. 7.1.

XI. LIST OF PROPOSED TRIAL EXHIBITS

A. Plaintiffs' Exhibit List

Plaintiffs' exhibit list is attached as Exhibit G.

Plaintiffs reserve the right to amend this list (i) in response to a witness list, deposition designations and/or listed exhibits provided by any other party (and any changes thereto), (ii) in response to the Court's rulings on the parties' motions *in limine* or other evidentiary rulings, or (iii) for other good cause shown. Plaintiffs reserve the right to object to the introduction and/or admissibility of any document on any exhibit list. Inclusion of a document on Plaintiffs' exhibit list is not intended to be a waiver of Plaintiffs' joint or individual rights to object to the introduction and admissibility of that document for any purpose or to object to any particular category or type of evidence. The Plaintiffs further reserve the right to (i) withdraw any exhibit, (ii) to prepare a summary of data, dates and/or events in accordance with applicable rule, and to submit such summary in evidence, (iii) to use diagrams, charts and other demonstratives in aid of testimony at the trial, (iv) to compel Astellas to provide an original of a document on a stated case-by-case basis, (v) to substitute any exhibit with an identical copy as produced by Astellas in this case, (vi) to use any exhibit listed by Astellas, (vii) to use additional exhibits for purposes of rebuttal or impeachment.

B. Defendant's Objections to Plaintiffs' Exhibit List

Defendant's objections to Plaintiffs' exhibit list are attached as Exhibit H.

In addition to the specific objections asserted to Plaintiffs' exhibits in Exhibit F, Defendant objects to any exhibits provided after the parties' agreed-upon deadline for exchange of exhibits, as established in the Amended Scheduling Order (ECF No. 468) and the Joint Motion to Extend Certain Pretrial Dates (ECF No. 528), as untimely. Defendant further objects to the extent that Plaintiffs seek to offer exhibits that are not identified on Plaintiffs' exhibit list. Defendant disagrees that the parties can supplement exhibit lists outside of the previously agreed-upon procedure for exchanging exhibit lists, the Federal Rules, and the Amended Scheduling Order. Defendant reserves its right to object to the use or admissibility of any exhibit that has not been identified in Plaintiffs' exhibit list.

Defendant objects to Plaintiffs' exhibit list and their reservations of rights to the extent that they fail to comply with the Federal Rules and the Amended Scheduling Order. Defendant further objects to Plaintiffs' reservation of right to "object to the introduction and/or admissibility of any document on any exhibit list" to the extent that it seeks to allow Plaintiffs the opportunity to raise or assert objections that should have been specifically asserted in Exhibit H or pursuant to the previously agreed-upon procedure for objecting to exhibits. (ECF No. 468, Amended Scheduling Order at 4-5.)

Defendant reserves its right to revise these objections, and to assert new objections, based on the Court's rulings (including but not limited to rulings on motions *in limine* and the Court's November 25, 2014 Order (Dkt. 611)), Plaintiffs' use of these exhibits, and evidence introduced at trial. Defendant's objections should not be construed as admissions that a particular exhibit is inadmissible if offered by Defendant. Regardless of whether Defendant has objected to Plaintiffs' exhibits, Plaintiffs must lay an adequate foundation for their exhibits at trial as a prerequisite to admission into evidence. Defendant reserves its right to assert objections at trial based on lack of foundation and other objections permissible under the Federal Rules of Evidence.

C. Defendant's Exhibit List

Defendant's exhibit list is attached as Exhibit I.

D. Plaintiffs' Objections to Defendant's Exhibit List

Plaintiffs' objections to Defendant's exhibit list are attached as Exhibit J. Further objections to Defendant's exhibits are encompassed by motions listed in Exhibit D.

E. Exhibit Objection Abbreviations

A key to the abbreviations employed by the parties in their respective objections to exhibit lists attached as Exhibit K.

Dated: November 26, 2014

Respectfully submitted,

/s/ Thomas M. Sobol

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